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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,664	08/30/2001	Kevin P. Baker	P2548P1C8	2448

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/943,664	BAKER ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *21 June 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): the rejections under 112, second paragraph.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *25-34 and 36*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: The basis for these rejections is set forth at pp. 3-6 of previous Office Action (Paper No. 15, 24 March 2003), and pp. 5-7 of the previous Office Action, paper No. 17, and the Office Action mailed Sept. 24, 2003. The amendment does not overcome the rejections under 35 USC §§ 101 and 112, first paragraph, for reasons discussed in the prior office actions and below. Applicants' assertion on pages 5-6 of the response that the claimed polypeptide has utility even if the polypeptide is encoded by a gene that is amplified in cancer and the polypeptide is not over-expressed, because this very absence of over-expression still provides significant information for cancer diagnosis and treatment, has been fully considered but are not deemed persuasive. It has not been demonstrated that the protein of the instant invention is differentially expressed in different tumors. If it was, the protein would have a specific and substantial utility for tumor classification, but the mere assertion that it may be differentially expressed does not provide a specific and substantial utility, and is an invitation to experiment. The argument that if a gene is amplified but the gene product is not over-expressed, the clinician would accordingly will decide not to treat a patient with agents that target the gene product is also insufficient to overcome the rejection of the claims. If a specific gene product was known to be involved in cancer and if there were known compounds that could be used to target the gene product, this would be an acceptable utility. However, the gene product of the instant invention has not been demonstrated to be involved in cancer. Over-expression of a gene product in a cancer cell does not necessarily mean that the gene product is involved in the cancer and that targeting the gene product would be therapeutic. Additionally, there are no known compounds that would target the gene product. Applicants' arguments on pages 6-9 of the response that the polypeptide also has a specific and substantial utility, as well as a well-established and credible utility, in that it can be used to create degenerative oligonucleotide probes, which can be used to isolate genomic and cDNA nucleotide sequences, have been fully considered but are not deemed persuasive. The polypeptide is not used to create degenerative oligonucleotide probes; it is knowledge of the sequence of the protein that can be used to design oligonucleotide probes. Therefore this is not a utility of the polypeptide. Additionally, the sequence of any polypeptide could be used as such, and further, the nucleic acid sequence encoding the polypeptide is already known. Applicants' argue on page 10 of the response that variants of 95% sequence identity are enabled, because the variants must also be encoded by a nucleic acid that is amplified in lung or colon tissue, and therefore all claimed variants might also be used to create degenerative oligonucleotide probes capable of identifying and isolating nucleic acids that are overexpressed in lung or colon tumors. Applicants' arguments have been fully considered but are not deemed persuasive. To determine which polypeptides with at least 95% sequence identity to the protein of SEQ ID NO: 50 and are also encoded by a nucleic acid that is amplified in lung or colon tissue would require significant further research, and therefore would require undue experimentation. Applicants' on pages 11-12 argue that the Guidelines for Examination of Patent Applications under 35 USC §§ 112, first paragraph, support that the written description requirement is satisfied for claims 25-26, 33 and 34, and that the latter claim in Example 13 of the Training Materials is analogous to claims 25, 26 and 36 of the present application, and that the rejection of claims 25, 26 and 36 is not proper because the present specification and claims do indicate distinguishing attributes that are shared by members of the claimed genus, that of being encoded by a nucleic acid that is amplified in lung or colon tumors, and that the specification at page 103 and Figure 20 discloses several structural features common to species falling with the claimed genus. Applicants' arguments have been fully considered but are not deemed persuasive. The latter claim in Example 13 of the Training Materials is drawn to a variant of the protein of SEQ ID NO: 3, and the training materials conclude that there are no common structural features that distinguish compounds in the genus from others in the protein class, and the disclosure fails to describe the common attributes or characteristics that identify members of the genus. In the instant case, the specification and claim indicate the distinguishing attribute of being encoded by a nucleic acid that is encoded by a nucleic acid that is amplified in lung or colon tumors; however, this is not an attribute of the protein, and is therefore not a distinguishing attribute as encompassed by the Training Materials. Applicants' arguments on pages 12-13 of the response that they have overcome the utility rejection based on arguments presented in the present response, and therefore have overcome the rejection under 35 USC § 102, have been fully considered but are not deemed persuasive, because of the reasons discussed above. For these reasons and those discussed previously, the rejections are maintained.

Applicants' amendment to the claims has been entered and has overcome the rejections under 35 USC 112, second paragraph.

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